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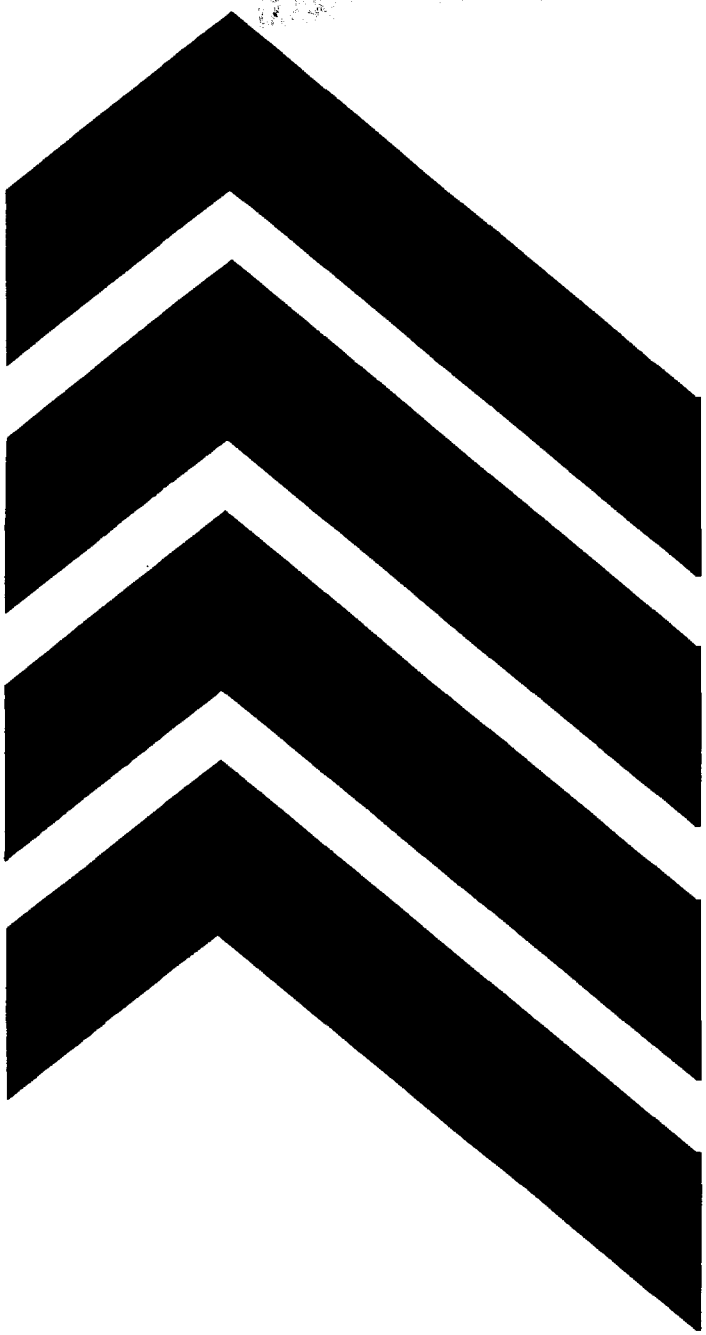
NVLAP®

National
Voluntary
Laboratory
Accreditation
Program



Procedures and General Requirements

NIST HANDBOOK 150

U.S. Department of Commerce
Technology Administration
National Institute of Standards
and Technology

The National Institute of Standards and Technology was established in 1988 by Congress to "assist industry in the development of technology . . . needed to improve product quality, to modernize manufacturing processes, to ensure product reliability . . . and to facilitate rapid commercialization . . . of products based on new scientific discoveries."

NIST, originally founded as the National Bureau of Standards in 1901, works to strengthen U.S. industry's competitiveness; advance science and engineering; and improve public health, safety, and the environment. One of the agency's basic functions is to develop, maintain, and retain custody of the national standards of measurement, and provide the means and methods for comparing standards used in science, engineering, manufacturing, commerce, industry, and education with the standards adopted or recognized by the Federal Government.

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- Advanced Systems

Computing and Applied Mathematics Laboratory
- Applied and Computational Mathematics[2]
- Statistical Engineering[2]
- Scientific Computing Environments[2]
- Computer Services[2]
- Computer Systems and Communications[2]
- Information Systems

[1] At Boulder, CO 80303.
[2] Some elements at Boulder, CO 80303.

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National Voluntary Laboratory Accreditation Program

Procedures and General Requirements

James L. Cigler and Vanda R. White, Editors

March 1994

U.S. Department of Commerce
Ronald H. Brown, Secretary

Technology Administration
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PREFACE

NIST Handbook 150 is intended for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for accreditation under the National Voluntary Laboratory Accreditation Program (NVLAP). It presents the basic procedures and general accreditation requirements of NVLAP for use in accrediting calibration and testing laboratories.

This handbook contains Part 285 of Title 15 of the U.S. Code of Federal Regulations (CFR), "National Voluntary Laboratory Accreditation Program Procedures and General Requirements," plus all general procedures, criteria, and policies formerly contained in the individual NVLAP technical handbooks and separately published NVLAP policies. This organization of the material was adopted so that users of the handbook can readily access all general accreditation requirements for a given subject in one place. Subpart D, Sections 285.33(a) through (n), is essentially identical to the language of ISO Guide 25, "General requirements for the competence of calibration and testing laboratories."

A small black triangle appears in the left-hand margin of selected lines of text throughout this handbook; the marked text applies only to the Calibration Laboratory Accreditation Program (LAP). In Sections 285.33(a) through (n), the marked text additions result from NVLAP interpretation of ISO Guide 25 via ANSI/NCSL Z540-1-1994 (draft). Section 285.33(o), based in large part on the requirements of MIL-STD-45662A, was added in its entirety as contained in ANSI/NCSL Z540-1-1994 (draft) for assessment of quality systems for the control of Measuring and Test Equipment (M & TE).

A brief review of the evolution of the current CFR Part 285 follows:

> The NVLAP Procedures and General Requirements were first published in the *Federal Register* on February 25, 1976, and became effective on that date. The *Federal Register* notice stated: "The purpose of this part (...of the CFR...) is to establish procedures under which a National Voluntary Laboratory Accreditation Program will function."
>
> The Procedures were revised on December 10, 1984 and again on September 12, 1990, and a notice of proposed revisions was published in the *Federal Register* on July 27, 1993.
>
> ***December 10, 1984 Revision.*** A revision of the Procedures was published in the *Federal Register* on November 8, 1984 to become effective on December 10, 1984. The *Federal Register* notice cited four major reasons for revising the NVLAP Procedures:
>
> "First, the steps involved in establishing a laboratory accreditation program (LAP) and operating NVLAP needed to be streamlined to increase efficiency and to reduce costs. Budget constraints made this streamlining imperative. Second, large portions of Parts 7a, 7b, and 7c were repetitious. Consolidating the comparable sections of each part into one section reduces the total amount of text and makes the NVLAP Procedures easier to read and follow. Third, the accreditation criteria need to be updated in light of the recent developments by national and international bodies, particularly as reflected in the International Organization for Standardization (ISO) document ISO Guide 25 (revised),

"General Requirements for the Technical Competence of Testing Laboratories," and ASTM E548, "Criteria for the Evaluation of Testing and Inspection Agencies." Fourth, since interaction with national laboratory accreditation systems of other countries is becoming increasingly important in fostering international trade, reciprocal recognition of accredited laboratories requires similar criteria and procedures."

September 12, 1990 Revision. The Omnibus Trade and Competitiveness Act of 1988 (Public Law No. 100-418) renamed the National Bureau of Standards (NBS) as the National Institute of Standards and Technology (NIST). A subsequent reorganization of NIST transferred certain responsibilities of the Office of Standards Services (OSS) to the National Voluntary Laboratory Accreditation Program (NVLAP). On September 12, 1990, authority was granted to amend the NVLAP Procedures to reflect the name change and the transfer of responsibilities.

March 1994 Revision. This revision was made for the following reasons:

1. To expand the procedures to include accreditation of calibration laboratories following establishment of the Calibration LAP (*Federal Register* notice Monday, May 18, 1992).

2. To update the Procedures to ensure compatibility with generally accepted conformity assurance and conformity assessment concepts.

3. To incorporate international changes, especially to be consonant with relevant International Organization for Standardization (ISO) documents (e.g., ISO Guides 25, 38, 43, and 58, and the ISO 9000 series of standards). NVLAP accreditation actions conform to ISO Guide 58, and laboratories accredited by NVLAP fulfill the ISO 25 guidelines.

4. To facilitate and promote acceptance of calibration and test results between countries to avoid barriers to trade. Provisions in this regard will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, harmonize standards and procedures, and establish the basis for bilateral and multilateral agreements.

Any questions or comments on this handbook should be submitted to the National Institute of Standards and Technology/NVLAP, Building 411, Room A162, Gaithersburg, MD 20899; phone (301) 975-4016; FAX (301) 926-2884.

ACKNOWLEDGMENTS

The preparation of this document has been a joint effort, with the input of representatives from other government agencies, laboratories, and the private sector. Acknowledgment of their efforts is in order; however, the listing of all of the individual names is impossible. The submissions by individuals and companies of letters offering suggestions for improvement to this document were also very welcome, as were the contributions of those who attended the public workshops.

Special recognition is made of the considerable contributions of David F. Alderman, Jeffrey Horlick, Lawrence S. Galowin, and S. Wayne Stiefel of the NVLAP staff in the revisions to the NVLAP Code of Federal Regulations and the augmenting material of this publication; their knowledge and judgment were essential for the comprehensive scope achieved. Major contributions were made by Jon M. Crickenberger and C. Douglas Faison, who coordinated the addition of material specific to the Calibration Laboratory Accreditation Program (LAP).

Several NIST measurement divisions, members of the National Conference of Standards Laboratories (NCSL) Total Quality Management (TQM) Committee and its chairman, Gary Davidson, are recognized for their tireless efforts. Special thanks are given to Joe D. Simmons, Chief of the NIST Calibration Program, and Norman B. Belecki, Group Leader in the NIST Electricity Division, for their contributions to broadening the NVLAP procedures to embrace the special features required for a comprehensive Calibration LAP.

Sincere appreciation for prepublication support is extended to Sherrie L. Abrecht, Leslie T. King, Maria A. Lancaster, Channing L. Monti, Margaret G. Musick, and Lisa Warfield of the NVLAP administrative staff.

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SUBPART A - GENERAL INFORMATION

Sec. 285.1 Purpose

The purpose of Part 285 of the Code of Federal Regulations is to set out procedures and general requirements under which the National Voluntary Laboratory Accreditation Program (NVLAP) operates as an unbiased third party to accredit both calibration laboratories and testing laboratories in response to:

(a) mandates by the Federal Government through legislative or administrative action;

(b) requests from a government agency (Section 285.13); and

(c) requests from a private sector organization (Section 285.14).

Supplementary technical and administrative requirements are provided in supporting handbooks and documents as needed depending on the criteria established for specific Laboratory Accreditation Programs (LAPs).

Sec. 285.2 Organization of procedures

Subpart A describes considerations which relate in general to all aspects of NVLAP. Subpart B describes how new LAPs are requested, developed, and announced, and how LAPs are terminated. Subpart C describes procedures for accrediting laboratories. Subpart D sets out the conditions and criteria for NVLAP accreditation.

Sec. 285.3 Description and goal of NVLAP

(a) NVLAP is a system for accrediting calibration laboratories and testing laboratories found competent to perform specific tests or calibrations. Competence is defined as the ability of a laboratory to meet the NVLAP conditions (Section 285.32) and to conform to the criteria (Section 285.33) in NVLAP publications for specific calibration and test methods.

(b) NVLAP is a process which:

(1) provides the technical and administrative mechanisms for national and international recognition for competent laboratories based on a comprehensive procedure for promoting confidence in calibration and testing laboratories that show that they operate in accordance with NVLAP's requirements;

NOTE: NVLAP operates under a Quality Management System to ensure that the NVLAP program meets the requirements of the U.S. Code of Federal Regulations (as augmented), and the various international standards for laboratory accreditation and quality management (see Section 285.4, *References*).

(2) provides laboratory management with documentation for use in the development and implementation of their quality systems;

(3) identifies competent laboratories for use by regulatory agencies, purchasing authorities, and product certification systems;

(4) provides laboratories with guidance from technical experts to aid them in reaching a higher level of performance, resulting in the generation of improved engineering and product information; and

(5) promotes the acceptance of calibration and test results between countries, and facilitates cooperation between laboratories and other bodies to assist in the exchange of information and experience, facilitating removal of non-tariff barriers to trade and promoting the harmonization of standards and procedures.

(c) NVLAP is comprised of a series of laboratory accreditation programs (LAPs) which are established on the basis of requests and demonstrated need. The specific calibration and test methods, types of calibration and test methods, products, services, or standards to be included in a LAP are determined by an open process during the establishment of the LAP (see Section 285.11).

The U.S. Department of Commerce, National Institute of Standards and Technology, formerly the National Bureau of Standards (NBS), administers NVLAP.

The Director of the National Institute of Standards and Technology (NIST) does not unilaterally propose or decide the scope of a LAP. Communication with other laboratory accreditation systems is fostered to encourage development of common criteria and approaches to accreditation and to promote the domestic, foreign, and international acceptance of test data produced by the accredited laboratories.

(d) NVLAP programs are established:

(1) for public and private calibration and testing laboratories, including commercial laboratories, manufacturers' in-house laboratories, university laboratories, and federal, state, and local government laboratories;

(2) to meet legal requirements, regulations or codes, and contract specifications, or to be recognized as demonstrably competent to meet the needs of its clients; and

(3) as the basis for guidance to facilitate agreements on mutual recognition of accreditation of laboratories between NVLAP and other accreditation organizations.

(e) NVLAP accreditation is:

(1) based on evaluation of a laboratory's technical qualifications and competence for conducting specific test methods, measurements and services in specified fields of calibration or testing;

(2) granted only after thorough evaluation of the applicant has demonstrated that all NVLAP criteria have been met;

(3) acknowledged by the issuance of two documents to attest to that compliance: (1) a Certificate of Accreditation, and (2) a Scope of Accreditation which details the specific test methods, measurements and services for which a laboratory has been accredited;

(4) administered in a nondiscriminatory manner;

(5) not conditional on the size of the laboratory or on its membership in any association or group; and

(6) based on assessing the competence of the laboratory against all of the NVLAP requirements.

Sec. 285.4 References

NVLAP is designed to be compatible with domestic and foreign laboratory accreditation programs to ensure the universal acceptance of test data produced by NVLAP-accredited laboratories. In this regard, these procedures are compatible with:

(a) the most recent official publications of ISO Guides 2, 25, 30, 38, 43, 45, 49, 58, and Standards 8402, 9001, 9002, 9003, and 9004;

(b) *International vocabulary of basic and general terms in metrology (VIM)*, and *Guide to the expression of uncertainty in measurement*, issued by International Bureau of Weights and Measures (BIPM), International Electrotechnical Commission (IEC), International Federation of Clinical Chemistry (IFCC), International Organization for Standardization (ISO), International Union of Pure and Applied Chemistry (IUPAC), International Union of Pure and Applied Physics (IUPAP), and International Organization of Legal Metrology (OIML);

(c) the most recent official publications of ISO Guidelines 10011-1 and 10011-2;

(d) MIL-STD 45662A; Calibration System Requirement; 1988;

(e) NIST Technical Note 1297; *Guidelines for Evaluating and Expressing Uncertainty of NIST Measurement Results*; 1993; and

(f) NCSL Recommended Practice #7; *Laboratory Design*; July 25, 1993.

Sec. 285.5 Definitions

Accreditation (of a laboratory): A formal recognition that a laboratory is competent to carry out

specific tests or calibrations or types of tests or calibrations.

Accreditation criteria: A set of requirements used by an accrediting body which a laboratory must meet in order to be accredited.

Approved Signatory (of an accredited laboratory): An individual who is recognized by NVLAP as competent to sign accredited laboratory calibration or test reports.

NOTE: The Approved Signatory is responsible for the technical content of the report and is the person to be contacted by NVLAP, laboratory clients, or others in case of questions or problems with the report. Approved Signatories shall be persons with responsibility, authority and technical capability within the organization for the results produced. The laboratory must maintain a list of Approved Signatories and make that list available for review during on-site assessments and to NVLAP upon request.

Assessment (of a laboratory): The on-site examination of a testing or calibration laboratory to evaluate its compliance with the conditions and criteria for accreditation.

Authorized Representative (of an accredited laboratory): An individual who is authorized by the laboratory or the parent organization to sign the NVLAP application form and commit the laboratory to fulfill the NVLAP requirements. (The Authorized Representative may also be recommended by the laboratory as an Approved Signatory.)

NOTE: The laboratory must designate an Authorized Representative who has authority to sign the NVLAP application and commit the laboratory to fulfill the NVLAP requirements. Only the Authorized Representative can authorize a change in the scope or nature of the laboratory's application. This person is listed in NVLAP directories and will receive all correspondence and inquiries from NVLAP.

Calibration: A set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a measurand.

NOTES:

(a) The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system, or the assignment of values to marks on arbitrary scales.

(b) A calibration may also determine other metrological properties.

(c) The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.

(d) The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve.

Calibration certificate or report: Document that presents calibration results and other information relevant to a calibration.

Calibration method: A defined technical procedure for performing a calibration.

Certificate of Accreditation: A document issued by NVLAP to a laboratory that has met the criteria and conditions for accreditation. The Certificate of Accreditation may be used as proof of accredited status. A Certificate of Accreditation is always accompanied with a Scope of Accreditation.

Client: Any person or organization that engages the services of a testing or calibration laboratory.

Competence: The ability of a laboratory to meet the NVLAP conditions and to conform to the criteria in NVLAP publications for specific calibration and test methods.

Deficiency: The non-fulfillment of NVLAP conditions and/or criteria for accreditation.

Director of NIST: The Director of the National Institute of Standards and Technology or designate.

Error: The difference between the true and measured value of a quantity.

Interlaboratory comparisons: Organization, performance and evaluation of calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Influence quantity: A quantity which is not the subject of the measurement but which influences the value of the measurand or the indication of the measuring instrument. Examples: ambient temperature; frequency of a measured alternating voltage.

Laboratory: An organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

NOTE: NVLAP further defines "laboratory" as being a physical entity; that is, a testing or calibration facility that is separate and apart physically from any other laboratory whether or not sharing common ownership, management, or quality systems with any other laboratory(s).

NVLAP previously differentiated between "main facilities" and "sub-facilities." This distinction is no longer recognized. (Exception: As long as there is no break in accreditation, any laboratory previously accredited as a "sub-facility" may request to be "grandfathered" in its accreditation renewal under the former classification as a "sub-facility," including the unique conditions associated with that classification.)

Any variation from this policy, other than the "grandfathering" exception, must be evaluated on its own merits. NVLAP reserves the right to decide whether or not to recognize variations.

Laboratory accreditation body: Body that conducts and administers a laboratory accreditation system and grants accreditation.

Laboratory accreditation system: System that has its own rules of procedure and management for carrying out laboratory accreditation.

LAP: A laboratory accreditation program established and administered under NVLAP, consisting of test methods or calibrations relating to specific products or fields of testing or calibration.

Limits of permissible error (of a measuring instrument): The extreme values of an error permitted by specifications, regulations, etc., for a given measuring instrument.

NOTE: This term is frequently referred to as "tolerance" in the United States.

Measurand: A quantity subjected to measurement.

NOTE: As appropriate, this may be the "measured quantity" or the "quantity to be measured."

Measurement: The set of operations having the object of determining the value of a measurand.

Measurement assurance: A process to ensure adequate measurement results that may include, but is not limited to: 1) use of good experimental design principles so that the entire measurement process, its components, and relevant influence factors can be well characterized, monitored, and controlled; 2) complete experimental characterization of the measurement process uncertainty including statistical variations, contributions from all known or suspected influence factors, imported uncertainties, and the propagation of uncertainties throughout the measurement process; and 3) continuously monitoring the performance and state of statistical control of the measurement process with proven statistical process control techniques including the measurement of well-characterized check standards along with the normal workload and the use of appropriate control charts.

Measuring and test equipment: All of the measuring instruments, measurement standards, reference materials, auxiliary apparatus and instructions that are necessary to perform a measurement. This term includes measuring equipment used in the course of testing and inspection, as well as that used in calibration.

NOTE: In the context of this handbook, the term "measuring and test equipment" is taken to encompass "measuring instruments" and "measurement standards." Moreover, a "reference

material" is considered to be a type of "measurement standard."

Measuring instrument: A device intended to make a measurement, alone or in conjunction with supplementary equipment.

NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

NVLAP Lab Code: A unique alphanumeric identifier assigned by NVLAP to each applicant laboratory; e.g., 1000 or 1000-00. It is used by NVLAP for identification, recordkeeping, and data base management. A laboratory uses its Lab Code in all correspondence with NVLAP. The Lab Code is cross-referenced with the laboratory's name, laboratory accreditation program (LAP), and geographic location in the NVLAP annual directory.

Person: Associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies—as well as divisions thereof—and individuals.

Precision: The repeatability of measurement data; the similarity of successive independent measurements of a single magnitude generated by repeated applications of a process under specified conditions.

Product: A type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing: The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Quality audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

NOTE: The quality audit typically applies, but is not limited, to a quality system or elements thereof, to processes, to products, or to services. Such audits are often called "quality system audit," "process quality audit," "product quality audit," or "service quality audit."

Quality manual: A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Quality system review: A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and new objectives resulting from changing circumstances.

Reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, for the assessment of a measurement method, or for assigning values to materials. A "certified reference material" means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

Resolution: The smallest discrete or discernible change in a value that can be measured.

Revocation: Revocation is the removal of the accredited status of a laboratory when it is found to have violated the terms of its accreditation.

Scope of accreditation: A document issued by NVLAP which lists the test methods or services, or calibration services for which the laboratory is accredited.

Stability: The ability of a measuring instrument to maintain constant its metrological characteristics.

NOTE: It is usual to consider stability with respect to time. Where stability with respect to another quantity is considered, this should be stated explicitly.

Standard, international (measurement): A standard recognized by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned.

Standard, measurement: A material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

Standard, mutual consent: An artifact or process that is used as a de facto standard by mutual consent of the supplier and customer when no recognized U.S. national or international standard is available.

Standard, national (measurement): A standard, recognized by a national decision, to serve in a country as the basis for assigning values to standards of the quantity concerned.

Standard, primary: A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Standard, reference: (See definition of *Reference standard*.)

Standard, secondary: A standard whose value is assigned by comparison with a primary standard of the same quantity.

Standard, transport (or transfer): A standard used as an intermediary to compare standards.

Standard, working: A standard usually calibrated against a reference standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials.

Statistical Process Control (SPC): A systematic process for monitoring the validity of a calibration or the value of a laboratory standard using statistical tools as a basis for decision.

Sub-facility: A laboratory operating under the technical direction and quality system of a main facility that is accredited.

Suspension: Suspension is a temporary removal of the accredited status of a laboratory when it is found to be out of compliance with the terms of its accreditation.

Test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

Test method: A defined technical procedure for performing a test.

Testing laboratory: A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products or materials.

Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Traceability of the accuracy of measuring instruments: A documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

Uncertainty of measurement: Parameter, associated with the result of a measurement, that characterizes

the dispersion of the values that could reasonably be attributed to the measurand.

Uncertainty, Type A (evaluation of): Method of evaluation of uncertainty by the statistical analysis of series of observations.

Uncertainty, Type B (evaluation of): Method of evaluation of uncertainty by means other than the statistical analysis of series of observations.

Verification: Confirmation by examination and provision of evidence that specified requirements have been met.

NOTES:

(a) In connection with the management of measuring equipment and/or processes, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the limits of permissible error defined in a standard, regulation or specification peculiar to the management of the measuring equipment and/or processes.

(b) The result of verification leads to a decision either to restore to service, or to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases documentation of the verification performed is kept on the measuring instrument's individual record.

(c) The verification process is frequently referred to as "calibration" in the United States.

Sec. 285.6 NVLAP documentation

NVLAP publications are available for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for accreditation under the NVLAP program. Accredited laboratories will be sent revised publications routinely. Publications include:

(a) the Procedures and General Requirements, (15 CFR Part 285);

(1) United States Code of Federal Regulations (CFR)

The primary document describing the legal basis for NVLAP, including procedures for establishing accreditation activities and the criteria and general requirements for accreditation of laboratories, is contained in the U.S. Code of Federal Regulations, Title 15 - Commerce and Foreign Trade, Subtitle B - Regulations Relating to Commerce and Foreign Trade, Chapter II - National Institute of Standards and Technology, Part 285 - "National Voluntary Laboratory Accreditation Program Procedures and General Requirements." CFR Part 285 is available as a reprint of the U.S. Code, and is incorporated in official NIST publications.

(2) NIST Handbook 150

NIST Handbook 150 contains the U.S. Code [(1) above] plus additional material specifying NVLAP interpretation of the U.S. Code related to calibration and testing laboratory programs.

(b) handbooks containing the administrative and operational procedures and technical requirements for specific LAPs;

A series of handbooks in the 150 series (i.e.; 150-1 ..... n) provides technical guidance, criteria and requirements for calibration and testing laboratories. A separate handbook is published for each Laboratory Accreditation Program (LAP) or unique field of testing (e.g., anyone interested in the general and specific procedures and requirements for the Energy Efficient Lighting Products LAP needs NIST Handbook 150 plus NIST Handbook 150-1, *Energy Efficient Lighting Products, Lamps and Luminaires*). Amplifying technical information related to specific fields of calibration is also published as part of the series (e.g., *Calibration Laboratories Technical Guide*).

(c) a directory of accredited laboratories, published annually and updated periodically;

The annual directory contains the name and address, Authorized Representative, phone number, scope of accreditation, and the accreditation renewal date for

each accredited laboratory. The directory is distributed nationally and internationally to participating laboratories, manufacturers, suppliers, retailers, professional and trade associations, standards groups, and government agencies.

(d) Policy Guides that provide changes to the Procedures and General Requirements and Handbooks between formal revisions of those publications.

Sec. 285.7 Confidentiality

To the extent permitted by applicable laws, NVLAP will seek to ensure confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing, evaluation, and accreditation of laboratories.

Sec. 285.8 Referencing NVLAP accreditation

To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(a) Follow NVLAP guidance when advertising its accredited status (including the use of the NVLAP logo) on letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications.

(1) The term "NVLAP" and the NVLAP logo (NVLAP®) are federally registered trademarks of the National Institute of Standards and Technology and the federal government, which retain exclusive rights to their use.

(2) NIST reserves the right to control the quality of the use of the term "NVLAP" and of the logo itself.

(3) Use of the NVLAP logo on letterhead, brochures, and calibration or test reports, should be accompanied by the following: "Accredited by the National Voluntary Laboratory Accreditation Program for the specific scope of accreditation under Lab Code XXXX."

(4) Permission for advertising NVLAP accreditation and use of the logo is conditional on and limited to those cases of calibration or test reports that describe calibration or testing within the scope of NVLAP accreditation.

(5) The name of at least one Approved Signatory must appear on all calibration or test reports endorsed with the NVLAP logo or referencing NVLAP accreditation.

Laboratory calibration or test reports carrying the NVLAP logo need not be signed individually by the Approved Signatory, except when required by legislation, or a client, or for other legal reasons. Computer-generated forms may have the signatory's name printed along with the calibration or test results, as long as there is evidence that there is a system in place to ensure that the calibration or test reports can not be generated without consent/review of the Approved Signatory.

(6) Photographic and electronic copies of the logo are available from NVLAP upon request.

(b) Inform its clients that the laboratory's accreditation or any of its calibration or test reports in no way constitutes or implies product certification, approval, or endorsement by NIST.

Sec. 285.9 Information collection requirements

The information collection requirements contained in these procedures have been approved by the Office of Management and Budget under the Paperwork Reduction Act and have been assigned OMB control number 0693-0003.

SUBPART B - ESTABLISHING A LAP

Sec. 285.11 Requesting a LAP

(a) A request to establish a LAP must be made to the Director of NIST;

(b) Each request must include:

(1) the scope of the LAP in terms of products, calibration services, or testing services proposed for inclusion;

(2) specific identification of the applicable standards and test methods, including appropriate designations, and the organizations or standards-writing bodies having responsibility for them;

(3) a statement of the perceived need for the LAP including:

(i) technical and economic reasons why the LAP would benefit the public interest;

(ii) evidence of a national need to accredit calibration or testing laboratories for the specific scope beyond that served by an existing laboratory accreditation program in the public or private sector;

(iii) an estimate of the number of laboratories that are likely to seek accreditation; and

(iv) an estimate of the number and nature of the users of such laboratories; and

(4) a statement of the extent to which the requestor is willing to support necessary developmental aspects of the LAP with funding and personnel.

(c) NVLAP may request clarification of the information submitted according to paragraph (b) of this section.

(d) Before determining whether a LAP should be established, the Director of NIST shall publish a *Federal Register* notice of the receipt of a LAP request if the request complies with Section 285.11(b). The notice will:

(1) describe the scope of the requested LAP;

(2) indicate how to obtain a copy of the request; and

(3) state that anyone may submit comments on the need for a LAP to NVLAP within 60 days of the date of the notice.

(e) Following receipt of the identification of a mandate for a LAP based on legislative or administrative action, the Director shall publish a *Federal Register* notice:

(1) stating the purpose of the LAP including the national or international need;

(2) describing the general scope of the LAP;

(3) identifying government agencies having oversight; and

(4) providing information to any interested party wishing to be on the NVLAP mailing list to receive routine information on the development of the LAP.

(f) Consistent with applicable laws and regulations, the Director may negotiate and conclude agreements with the governments of other countries for NVLAP recognition of foreign laboratories. At a minimum, any agreement must provide that accredited foreign laboratories meet conditions for accreditation comparable to and consistent with those set out in these requirements.

Sec. 285.12 LAP development decision

(a) The Director of NIST shall establish all LAPs on the basis of need.

(1) A mandate to develop a LAP by NVLAP will be interpreted as a de facto decision to develop the specified LAP, and a LAP will be developed (or existing LAPs modified, if practical) following these procedures.

(2) Government agencies may document the need by using Section 285.13, and private sector organizations by using Section 285.14.

(b) After receipt of the request, the Director of NIST shall analyze it to determine if there is need for the requested LAP. In making this determination, the Director of NIST shall consider the following:

(1) the needs and scope of the LAP initially requested;

(2) the needs and scope of the user population;

(3) the nature and content of other relevant public and private sector laboratory accreditation programs;

(4) compatibility with the criteria referenced in Section 285.33;

(5) the importance of the requested LAP to commerce, consumer well-being, or the public health and safety;

(6) the economic and technical feasibility of accrediting laboratories for the calibration or test methods, types of calibration or test methods, products, services, or standards requested; and

(7) recommendations from written comments for altering the scope of the requested LAP by adding or deleting test methods, types of test methods, products, services, or standards.

(c) If the Director of NIST decides that a need has been demonstrated, and if resources are available to develop a LAP, NVLAP shall notify interested persons of the decision to proceed with development of a LAP.

(d) If the Director of NIST concludes that there is a need for a LAP but that there are no resources for development, NVLAP shall notify the requestor and other interested persons of the decision not to proceed until resources become available.

(e) If the Director of NIST decides that a need for a LAP has not been demonstrated, NVLAP shall notify the requestor and other interested persons of the decision and the reasons not to proceed with development of a LAP.

Sec. 285.13 Request from a government agency

(a) Any federal, state or local agency responsible for regulatory or public service programs established under statute or code, which has determined a need to accredit laboratories within the context of its programs, may request the Director of NIST to establish a LAP.

(b) Each request must be in writing and must include the information required in Section 285.11(b) and:

(1) a description of the procedures followed or a citation of the specific authority used to identify a need for a LAP; and

(2) for state and local government agencies, a statement explaining why the LAP should be of national scope.

(c) NVLAP may request clarification of the information required by Section 285.11(b).

(d) Before deciding to proceed with development of a LAP, the Director of NIST shall publish a *Federal Register* notice of the receipt of a LAP request. The notice will indicate how to obtain a copy of the request and will state that anyone may submit comments on the need for a LAP to the requesting government agency within 60 days of the date of the notice.

(e) NVLAP shall notify interested persons of the decision to proceed or not to proceed with development of a LAP.

Sec. 285.14 Request from a private sector organization

(a) Any private sector organization which has determined a need to accredit laboratories for specific products, calibrations, or testing services, may request the Director of NIST to establish a LAP if it uses procedures meeting the following conditions:

(1) public notice of meetings and other activities including requests for LAPs is provided in a timely fashion and is distributed to reach the attention of interested persons;

(2) meetings are open and participation in activities is available to interested persons;

(3) decisions reached by the private sector organization in the development of a request for a LAP represent substantial agreement of the interested persons;

(4) prompt consideration is given to the expressed views and concerns of interested persons;

(5) adequate and impartial mechanisms for handling substantive and procedural complaints and appeals are in place; and

(6) appropriate records of all meetings are maintained and the official procedures used by the private sector organization to make a formal request for a LAP are made available upon request to any interested person.

(b) Each request must be in writing and must include the information required in Section 285.11(b) and a description of the way in which the organization has met the conditions specified in paragraph (a) of this section.

(c) NVLAP may request clarification of the information required by Section 285.11(b).

(d) Before deciding to proceed with development of a LAP, the Director of NIST shall publish a *Federal Register* notice of the receipt of a LAP request. The notice will indicate how to obtain a copy of the request and will state that anyone may submit comments on the need for a LAP to the requesting private sector organization within 60 days of the date of the notice.

(e) NVLAP shall notify interested persons of the decision whether or not to proceed with development of a LAP.

Sec. 285.15 Development of technical requirements

(a) Technical requirements for accreditation are specific for each LAP. The requirements tailor the criteria referenced in Section 285.33 to the calibration or test methods, types of calibration or test methods, products, services, or standards covered by the LAP.

(b) NVLAP shall develop the technical requirements based on expert advice. This advice may be obtained through one or more informal public workshops or other suitable means.

(c) NVLAP shall make every reasonable effort to ensure that the affected calibration or testing community within the scope of the LAP is informed of any planned workshop. Summary minutes of each workshop will be prepared. A copy of the minutes will be made available for inspection and copying at the NIST Records Inspection Facility.

Sec. 285.16 Coordination with federal agencies

As a means of ensuring effective and meaningful cooperation, input, and participation by those federal agencies that may have an interest in and may be affected by established LAPs, NVLAP shall communicate and consult with appropriate officials within those agencies.

Sec. 285.17 Announcing the establishment of a LAP

(a) When NVLAP has completed the development of the technical requirements of the LAP and established a schedule of fees for accreditation, NVLAP shall publish a notice in the *Federal Register* announcing the establishment of the LAP.

(b) The notice will:

(1) identify the scope of the LAP; and

(2) advise how to apply for accreditation.

(c) NVLAP shall establish fees in amounts that will enable it to recover its full costs, and shall, from time to time as necessary, revise the fees for this purpose.

Sec. 285.18 Adding to or modifying an established LAP

(a) Established or developing LAPs may be added to, modified, or realigned based on either a written request from any person wishing to add or delete specific standards, calibration or test methods, or types of calibration or test methods or a need identified by NIST.

(b) NVLAP may choose to make the additions or modifications available for accreditation under a LAP when:

(1) the additional standards, calibration or test methods, or types of calibration or test methods requested are directly relevant to the LAP;

(2) it is feasible and practical to accredit calibration or testing laboratories for the additional standards, calibration or test methods, or types of calibration or test methods; and

(3) it is likely that laboratories will seek accreditation for the additional standards, calibration or test methods, or types of calibration or test methods.

(c) A laboratory requesting the addition of calibration parameters, test methods or services to its Scope of Accreditation must meet all NVLAP criteria for the additional calibration parameters, test methods or services; e.g., technical requirements, proficiency testing, payment of fees, etc. The need for an additional on-site assessment and/or proficiency testing will be determined on a case-by-case basis.

Sec. 285.19 Termination of a LAP

(a) The Director of NIST may terminate a LAP when the Director of NIST determines that a need no longer exists to accredit laboratories for the services covered under the scope of the LAP. In the event that the Director of NIST proposes to terminate a LAP, a notice will be published in the *Federal Register* setting forth the basis for that determination.

(b) The notice published under paragraph (a) of this section shall provide a 60-day period for submitting written comments on the proposal to terminate the LAP. All written comments will be made available for public inspection and copying at the NIST Records Inspection Facility.

(c) After the comment period, the Director of NIST shall determine if public support exists for the continuation of the LAP. If public comments support the continuation of the LAP, the Director of NIST shall publish a *Federal Register* notice announcing the continuation of the LAP. In the absence of public support for continuation, the LAP will be terminated effective 90 days after the date of the published notice of intent to terminate the LAP.

(d) If the LAP is terminated, NVLAP will no longer grant or renew accreditations following the effective date of termination. Accreditations previously granted shall remain effective until their expiration date unless terminated voluntarily by the laboratory or revoked by NVLAP.

SUBPART C - ACCREDITING A LABORATORY

Sec. 285.21 Applying for accreditation

(a) A laboratory may complete and remit an application for accreditation in any of the established LAPs.

(1) A NVLAP application package is sent to a laboratory on request. It includes the ***General Application***, ***Program-Specific Application***, ***NVLAP Fee Schedule***, the ***Program Handbook***, and all documents needed for understanding of the NVLAP program and requirements. This could include relevant Technical Guides in the fields of calibration for which a laboratory has requested accreditation.

(2) The ***General Application*** must be completed and signed by the Authorized Representative of the laboratory. Before completing and signing the application, the Authorized Representative should review all documents and become familiar with NVLAP requirements.

(b) Upon receipt of a laboratory's application, NVLAP shall:

(1) acknowledge receipt of the application;

(2) request further information, if necessary;

(3) confirm payment of fees before proceeding with the accreditation process; and

(4) specify the next step(s) in the accreditation process.

(c) Accreditation of laboratories outside of the United States may require:

(1) translation of laboratory documentation into English;

NOTE: In cases where laboratory documents are not in English, or laboratory personnel do not speak English, it is the responsibility of the laboratory to provide a translator to assist the NVLAP assessor(s) during the on-site assessments. The translator will assist the assessor(s) in conversing directly with laboratory management and technical staff and in reviewing laboratory documentation. Documents such as quality assurance manuals, protocols, standards, and test reports sent to NVLAP prior to on-site assessments or reviewed during assessments need not be translated into English solely for NVLAP purposes.

(2) payment of additional traveling expenses for on-site assessments and proficiency testing;

NOTE: Some of the fees listed on the NVLAP Fee Schedule may be insufficient to cover the costs incurred by an applicant laboratory located outside the U.S. In such cases, the laboratory will be responsible for all additional costs incurred. Additional fees will be charged, if necessary, for travel by NVLAP assessor(s) outside of the U.S., for shipment of proficiency testing materials to the laboratories and for any additional administrative expenses. To ensure that the initial or renewal application is processed without delay, payment (in U.S. currency) of the appropriate listed fees should accompany the application. When all the additional costs associated with the application have been identified, an invoice for any additional fee amount owed will be sent to the laboratory.

(3) export licenses.

NOTE: For certain scientific and technical equipment to be exported from the United States, a license issued by the U.S. Department of Commerce may be required. If a laboratory uses such equipment, NVLAP requires that the laboratory possess, and show upon request, an export license. For export license information, contact the U.S. Department of Commerce, Export Administration, Exporter Assistance, P.O. Box 273, Washington, DC 20230, telephone (202) 482-4811, FAX (202) 482-3617.

(d) NVLAP Fees

NVLAP receives no appropriated public funds. NVLAP operates on a cost-reimbursable basis from fees paid by participating laboratories that apply for accreditation in specific NVLAP fields of testing or calibration. For fee calculation purposes, a field is considered to be any area of accreditation that is a separate line item on the NVLAP Fee Schedule (for example, GOSIP is a separate field of testing even though it is part of the Computer/Electronics program).

The fee structure incorporates five major fee categories:

(1) The *Initial Application Fee* covers costs associated with processing an applicant for the first time. It is paid only one time per laboratory and is due with the initial application for accreditation.

(2) The *Administrative/Technical Support Fee* covers costs associated with NVLAP and other NIST staff conducting the program in all areas for which accreditation is offered and for providing these services to participating laboratories.

This fee is due annually regardless of the accreditation status of a laboratory. Laboratories which have been enrolled in a program for more than 1 year and are not yet accredited will be invoiced annually for the Administrative/Technical Support Fee, based on the date the laboratory's initial application was accepted by NVLAP.

(3) The *On-Site Assessment Fee* covers costs incurred for on-site assessment visits. On-site assessments are conducted prior to initial accreditation and every 2 years thereafter; therefore, this fee is due only for a renewal year in which an assessment is scheduled.

NOTE: The optional use of a preassessment visit will be considered if it is decided that such a visit would result in a better definition of the scope of accreditation which has been requested by the laboratory. In such cases the preassessment costs will be charged to the laboratory in addition to the actual On-Site Assessment Fee.

A laboratory will be charged for an additional assessment visit if required as the result of deficiencies in meeting NVLAP technical criteria. The fee for this additional assessment visit is the same as the On-Site Assessment Fee on the NVLAP Fee Schedule.

A laboratory will not be charged separately for a monitoring visit, which may be initiated by NVLAP at any time during the accreditation period for cause or on a random selection basis.

(4) The *Proficiency Testing Fee* covers costs relating to the provision of proficiency test samples and artifacts, the collection and analysis of laboratory results, and reports to NVLAP staff.

The Proficiency Testing Fee, which is paid with a laboratory's initial or renewal application, covers the rounds of proficiency testing scheduled for a given year. If a laboratory has participated in the scheduled rounds of testing, but has not yet attained accreditation, it will be invoiced prior to each subsequent round of proficiency testing until it submits its first renewal application. If proficiency testing is performed every other year, the fee is due only in the year that testing is scheduled to be performed.

(5) The *Test Method Fee* covers incremental costs associated with technical support related to the number and complexity of test methods selected by a laboratory within a given program. This fee is charged per test method; therefore, the total Test Method Fee depends on the total number of test methods selected and varies from application to application within a program.

(e) Fee Refund Policy

This refund policy applies to laboratories that withdraw from the NVLAP program. It covers each of the five major fee categories as follows:

(1) The *Initial Application Fee* is nonrefundable.

(2) The amount of the *Administrative/Technical Support Fee* and the *Test Method Fee* to be refunded depends upon the length of time that has elapsed between the laboratory's renewal date and the date NVLAP was notified of the decision to withdraw.

*Time of withdrawal (# of months after renewal date)**	*Refund amount*
Less than 3 months	3/4
3 months to less than 6 months	1/2
6 months to less than 9 months	1/4
9 months or greater	No refund

* If a laboratory is seeking initial accreditation (i.e., has never been accredited for a specific program), the time of withdrawal will be counted as the number of months after the date the initial application was received.

(3) The *On-Site Assessment Fee* is refundable only if no on-site related costs have been incurred. Otherwise, costs incurred will be deducted from the On-Site Assessment Fee.

(4) The portion of the *Proficiency Testing Fee* for any proficiency testing planned but not sent to the laboratory, or for any proficiency testing that was not initiated, will be refunded. No refund will be given for artifacts sent but returned unmeasured by the laboratory.

Sec. 285.22 Assessing and evaluating a laboratory

(a) Information used to evaluate a laboratory's compliance with the conditions for accreditation set out in Section 285.32, the criteria for accreditation set out in Section 285.33, and the technical

requirements established for each LAP will include (not necessarily in this order):

(1) application and other material submitted by the laboratory (Section 285.32(b));

(2) on-site assessment reports;

(3) laboratory performance on proficiency tests;

(4) laboratory responses to identified deficiencies; and

(5) technical evaluation.

(b) NVLAP shall arrange the assessment and evaluation of applicant laboratories in such a way as to minimize potential conflicts of interest.

The laboratory will be contacted to schedule a mutually acceptable date for the on-site assessment *after payment* of the required fees and will be notified of any additional information which must be supplied, and of any applicable proficiency testing requirements which must be completed, for the technical evaluation.

(1) Technical Experts

NVLAP uses Technical Experts (TEs) as assessors and evaluators. They may be engineers or scientists currently active in the field, consultants, college professors or retired persons. They are selected on the basis of their professional and academic achievements, experience in the field of testing or calibration, management experience, and tact in dealing with people. Their services are generally contracted as required; they are normally not NVLAP staff members.

Assessors are TEs selected to conduct an on-site assessment of a particular laboratory on the basis of how well their individual experience matches the type of testing or calibration to be assessed, as well as absence of conflict of interest. The laboratory has the right to appeal the assignment of an assessor and may request an alternate.

Evaluators are TEs selected to review the record of the laboratory as a whole, including the application, assessment report, deficiencies, corrections to deficiencies, and proficiency test results. Based on the totality of the record, the evaluators recommend whether or not a laboratory should be accredited. The evaluators are matched to the type of testing or calibration being evaluated. Like assessors, evaluators are selected to avoid conflict of interest.

(2) On-Site Assessment

Before initial accreditation and every 2 years thereafter, an on-site assessment of each laboratory is conducted to determine compliance with the NVLAP criteria. NVLAP assigns an assessor or a team of assessors and provides the laboratory with a short biographical sketch of the assessor(s). A lead assessor will be assigned if needed. The laboratory may request an alternate assessor if a conflict of interest or prior business relationship exists.

Assessors use checklists provided by NVLAP so that each laboratory receives an assessment comparable to that received by others. However, assessors have some latitude to make judgments about a laboratory's compliance with the NVLAP criteria.

An assessment normally takes 1 to 5 days depending on the scope of the laboratory's application. Every effort is made to conduct an assessment with as little disruption as possible to the normal operations of the laboratory. During the assessment, the assessor meets with management and laboratory personnel, examines the quality system, reviews staff information, examines equipment and facilities, observes demonstrations of calibrations or testing, and examines calibration or test reports.

The assessor reviews laboratory records including resumes, job descriptions of key personnel, training, and competency evaluations for all staff members who routinely perform, or affect the quality of the calibration or testing for which accreditation is sought. The assessor need not be given information which violates individual privacy, such as salary, medical

information, or performance reviews outside the scope of the accreditation program. The staff information may be kept in the laboratory's official personnel folders or separate, official folders that contain only the information that the NVLAP assessor needs to review.

At the conclusion of the assessment, the assessor conducts an exit briefing to discuss observations and any deficiencies with the Authorized Representative and other responsible laboratory staff. A written assessment report, signed by the Authorized Representative to acknowledge receipt of the report, will be left with the laboratory, and a copy forwarded to NVLAP.

The final report submitted to the laboratory shall include as a minimum:

(i) date(s) of assessment;

(ii) the names of the person(s) responsible for the report;

(iii) the names and addresses of all the laboratory sites assessed;

(iv) the assessed scope of accreditation or reference thereto; and

(v) comments and/or deficiencies cited by the assessor(s) on the compliance of the laboratory with the accreditation requirements.

(3) Deficiency Notification and Resolution

A deficiency is the failure of a laboratory to meet a NVLAP criterion. Deficiencies may be determined during on-site assessments, monitoring visits, proficiency testing, NVLAP staff review, and technical evaluation. Laboratories are informed of deficiencies during the on-site assessment and through other correspondence.

When a laboratory is notified of deficiencies, it must respond in writing to NVLAP within 30 days of the notification. The response must provide documentation, signed by the Authorized Representative, that the specified deficiencies have either been corrected or include a plan of action to make corrections. The plan must include a list of actions, dates of completion, and responsible persons.

A currently accredited laboratory must submit a satisfactory response concerning resolution of deficiencies within 30 days of notification or face possible suspension or revocation of accreditation.

Calibration of test equipment, materials, computer software, or measuring system implementations (which have a critical effect on the function accredited) that are identified as deficient (fail to meet the NVLAP criteria) should not be used for further NVLAP-accredited calibration or testing until corrective action has been completed and documented. Evidence of correction must be sent to NVLAP.

If substantial deficiencies have been cited, NVLAP may require an additional on-site assessment, at additional cost to the laboratory, prior to granting accreditation. All deficiencies and resolutions will be subject to thorough review and corrective actions will be verified during subsequent assessments and technical evaluations.

(4) Proficiency testing

Proficiency testing is an integral part of the NVLAP accreditation process. The performance of calibrations or tests and reporting of results using proficiency testing provides NVLAP with a way to determine the overall effectiveness of the laboratory. Information obtained from proficiency testing helps to identify problems in a laboratory. When problems are found, NVLAP works with the laboratory staff to solve them.

Each field of calibration or testing has proficiency testing requirements. Proficiency testing using *interlaboratory* comparisons may utilize randomly selected specimens from a batch of uniform material, selected specimens with known properties and results, artifacts with similar properties that have not been